PTO/SB/08A (08-03)
Approved for use through 07/31/2008. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

substitute for form 1449/PTO

Sheet 1

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known				
Application Number	10/017,755			
Filing Date	October 30, 2001			
First Named Inventor	T. Shimizu			
Art Unit	1615			
Examiner Name	S. Tran			
Attorney Docket Number	2522 US2P			

U. S. PATENT DOCUMENTS							
Examiner Initials*	Cite No.1	Document Number Number-Kind Code ^{2 (F known)}	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
5.7		^{US-} 4,371,516	02-01-1983	John Wyeth & Brother Limited			
ĺ		^{US-} 5,795,909	08-08-1998	Neuromedica, Inc.	,		
		^{US-} 5,958,453	09-28-1999	Takeda Chemical Industries			
		^{US-} 5,900,428	05-04-1999	Astra Aktiebolag			
		^{US-} 6,248,357	06-19-2001	Takeda Chemical Industries			
		^{US-} 6,287,596	09-11-2001	Daiichi Pharmaceutical Co.			
		^{US-} 6,365,184	04-02-2002	AstraZeneca AB	·		
		^{US-} 6,328,994	12-11-2001	Takeda Chemical Industries			
SI		^{US-} 6,586,004	07-01-2003	Takeda Chemical Industries			
		US-					
		US-					
		US-					
		US-					
		US-					
		US-					
		US-					
		US-					
		US-			١		
		US-					

FOREIGN PATENT DOCUMENTS							
	Cite No.	Foreign Patent Document	cument Publication Date		Pages, Columns, Lines, Where Relevant Passages		
· ·		Country Code ³ "Number ⁴ "Kind Code ⁵ (# known)	MM-DD-YYYY	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	Mhere Relevant Passages Or Relevant Figures Appear	T	
giT		EP 0 336 298	03-30-1989	E. R. Squibb & Sons			
Ī		EP 0 345 787 /	06-08-1989	Warner-Lambert Company			
		EP 0 365 480 /	10-10-1989	CIBA-GEIGY AG		L	
		EP 0 438 147 x	01-17-1991	SCLAVO S.p.A.			
		EP 0 553 777 x	01-27-1993	Takeda Chemical Industries			
3.5		EP 0 638 310 /	07-26-1994	Bristol-Myers Squibb Co.		Т	

Exa	miner		Date		
		6 7	Considered	'4	110/05
3 Sign	ature	3 ,,	Considered	-	710703

*EXAMINER: Initial if reference considered, whether or not clation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the Individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

PTO/SB/08A (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

Sheet 2

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

of 4

Complete If Known **Application Number** 10/017,755 Filing Date October 30, 2001 First Named Inventor T. Shimizu Art Unit 1615 S. Tran **Examiner Name** 2522 US2P Attorney Docket Number

U. S. PATENT DOCUMENTS						
Examiner Initials*	Cite No.1	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
	<u> </u>	Number-Kind Code ^{2 (F known)}	 			
	l	US-				
		US-				
	i	US-				
		US-				
		US-				
		US-				
		US-				
		US-				
		US-		<u> </u>		
		US-				
		US-				
		US-				
		US-				
		US-				
		US-				
		ÜS-		•		
		US-				
		US-				
		US-				

FOREIGN PATENT DOCUMENTS							
	Cite Foreign Patent Document		Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages		
		Country Cods ³ "Number ⁴ "Kind Code ⁸ (# known)	MM-DD-YYYY		Or Relevant Figures Appear		
3.7		EP 0 745 382 ~	01-27-1995	Yamanouchi Pharmaceutical			
\top		EP 0 839 526 ~	10-29-1997	Takeda Chemical Industries			
		EP 0 890 359 ~	02-21-1997	Fujisawa Pharmaceutical Co.			
		EP 0 914 818	06-12-1997	Kyowa Hakko Kogyo Co., Ltd			
T		EP 0 922 464 /	07-10-1997	Daiichi Pharmaceutical Co.			
85		EP 0 965 339 /	11-14-1997	Ajinomoto Co., Inc.		Γ	

Examiner	0 T	Date	0/12/01-
Signature	3 11	Considered	5/10/03

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 'Applicant's unique citation designation number (optional). 'See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 'Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 'For Japanese patent documents, the Indication of the year of the reign of the Emperor must precede the serial number of the patent document. 'Kind of document by the appropriate symbols as Indicated on the document under WIPO Standard ST.16 if possible. 'Applicant is to place a check mark here if English language Translation is attached.

This collection of Information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Total College 1.0 Rev 1450 Alexandria VA 22313 1450 DO NOT SEND FEES OR COMPLETED EXPRESS. SEND and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

PTO/SB/08A (08-03)

Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE der the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

Sheet 3

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete It Known				
Application Number	10/017,755			
Filing Date	October 30, 2001			
First Named Inventor	T. Shimizu			
Art Unit	1615			
Examiner Name	S. Tran			
Attorney Docket Number	2522 US2P			

U. S. PATENT DOCUMENTS						
Examiner Initials*	Cite No.1	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Unes, Where Relevant Passages or Relevant Figures Appear	
	L	Number-Kind Code ^{2 (f known)}	ļ		r iguies Appeal	
	1	US-			·	
		US-				
		US-		•		
		US-				
-		US-				
-		US-				
	<u> </u>	US-				
		US-				
		US-				
		US-				
	i —	US-				
	 	US-				
		US-	1			
		US-				
		US-				
		US-				
	 	US-				
		US-	1 1	······································		
		US-				

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No.1	Cite Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages		
		Country Code ³ "Number ⁴ "Kind Code ⁵ (# known)	MM-DD-YYYY		Or Relevant Figures Appear		
7,2		WO 92/11001	07-09-1992	SOLVAY (Societe Anonyme)			
		JP 4 066 538 (Abstract Only) /	03-02-1992	Suntory Ltd.		V	
		JP 5 310 558 (Abstract Only) /	11-22-1993	Lion Corp.		~	
		JP 5 411 226 (Abstract Only) /	01-27-1979	Shinetsu Chemical Industries		V	
		JP 6 100 601 (Abstract Only) -	04-12-1994	Daicel Chemical Industries		~	
7,2		JP 6 305 962 (Abstract Only) /	04-21-1993	Taisho Pharmaceut Co. Ltd.		V	

	· · · · · · · · · · · · · · · · · · ·					
Examiner Signature	37	Date Considered	3	110/	5	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Nind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. Applicant is to place a check mark here if English language

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the Individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patant and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO/SB/08A (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

Sheet 4

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known			
Application Number	10/017,755		
Filing Date	October 30, 2001		
First Named Inventor	T. Shimizu		
Art Unit	1615		
Examiner Name	S. Tran		
Attorney Docket Number	2522 LIS2P		

			U. S. PATENT D	OCUMENTS		
Examiner Initials*	Cite No.1	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevan Figures Appear	
		Number-Kind Code ^{2 (1 troom)}			1 3000 7700	
	1	US-				
	Ī	US-				
		US-				
		US-				
		US-				
		US-				
		US-				
		US-				
	 	US-				
	 	US-				
	 	US-				
	 	ÜS-				
		US-	<u> </u>			
	 	US-				
		US-				
		US-		•		
		US-				
		US-				
	1	US-				

	Cite No.1	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	Π
		Country Code ³ Number ⁴ 'Kind Code ⁵ (# known)			Or Relevant Figures Appear	T [®]
SI		JP 7 017 853 (Abstract Only) •	01-20-1995	Akiyoshi Yanagida		~
5.7		JP 8 310 969 (Abstract Only)	11-26-1996	Lian Corp. (Lioy)		~
	<u> </u>					-
·					<u> </u>	

Examiner		Date	2/10/05
Signature	3 . T	Considered	5/6/03

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 'Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵Applicant is to place a check mark here if English language Translation is attached.

This collection of Information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO/SB/08B (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

Subati	e for form 144	9/PTO		ine required to respond to a collection of information unless it contains a valid OMB control number. Complete if Known		
TRAIRE				Application Number	10/017,755	
INFO	DRMAT	TON DIS	CLOSURE	Filing Date	October 30, 2001	
STA	STATEMENT BY APPLICANT			First Named Inventor	T. Shimizu	
				Art Unit	1615	
(Use as many sheets as necessary)			ecessary)	Examiner Name	S. Tran	
Sheet	1	of	1	Attorney Docket Number	2522 US2P	7

	NON PATENT LITERATURE DOCUMENTS	
Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	Watanabe, Y. et al., "New Compressed Tablet Rapidly Disintegrating in Saliva in the Mouth using Crystalline Cellulose and a Disintegrant", <u>Biol. Pharm. Bull.</u> (1995) Vol. 18, No. 9, pp. 1308-1310	
	-	
		,
	Cite No.1	Cite Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. Watanabe, Y. et al., "New Compressed Tablet Rapidly Disintegrating in Saliva in the Mouth using

	- <u></u>				
Examiner Signature	2.7	Date Considered	3/10	0/05	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:

Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.